# CHRONOLOGY OF MAJOR ACTIVITIES DURING REGULATORY REVIEW. RELATING TO IND 17,123

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Date		- •
January 10, 1980	Submission to FDA	IND 17,123 for Sodium Phenylacetate
January 24, 1980	Letter from FDA	Acknowledged receipt of IND 17,123
February 19, 1980	Submission to FDA	Amended IND 17,123
March 17, 1980	Submission to FDA	Amended IND 17,123
March 17, 1980	Letter from FDA	Request for additional information
March 21, 1980	Submission to FDA	Response with requested information
May 12, 1980	Letter from FDA	Acknowledgment of receipt of information and request regarding labels.
June 6, 1980	Submission to FDA	Labels sent in response to request.
June 13, 1980	Submission to FDA	Amended IND 17,123
August 18, 1980	Submission to FDA •	Amended IND 17,123
May 7, 1981	Submission to FDA	Annual Report
April 12, 1982	Submission to FDA	Annual Report
Undated	Letter from FDA	Request for additional information
June 8, 1982	Submission to FDA	Response to request information
November 3, 1982	Submission to FDA	Amended IND 17,123

February 2, 1983 Submission to FDA

Amended IND 17,123

May 24, 1983	Submission to FDA	Annual Report
November 28, 1983	Submission to FDA	Amended IND 17,123
July 23, 1984	Letter from FDA	· - ·
August 7, 1984	Submission to FDA	Amended IND 17,123
August 9, 1984	Submission to FDA	Amended IND 17,123
February 26, 1986	Letter from FDA	Letter re combined file IND 17,123 and 17,336
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# CHRONOLOGY OF MAJOR ACTIVITIES DURING REGULATORY REVIEW. RELATING TO IND 17,336

#### Date

March 17, 1980	Submission to FDA	IND 17,336 filed
April 2, 1980	Letter from FDA	Letter of acknowledgement
February 12, 1981	Letter from FDA	Request for additional information
Undated	Submission to FDA	Response to request for additional information
May 22, 1981	Submission to FDA	Annual Report
August 18, 1982	Submission to FDA	Amended IND 17,336
November 3, 1982	Submission to FDA	Letter regarding experimental protocol
February 3, 1983	Submission to FDA	Amended IND 17,336
April 22, 1982	Submission to FDA	Annual Report
August 17, 1984	Submission to FDA	Annual Report
October 1, 1984	Letter from FDA	Notification that IND transferred to different department
February 26, 1986	Letter from FDA	Letter re combined file IND 17,123 and 17,336

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#### NDA 19-530

#### Ucephan Oral Liquid

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DATE	SUBJECT	VOL.	IAB
02/25/86	Submitted samples and standards for Dallas and Atlanta.	1.1	OR.1
07/16/86	FDA letter requesting further clinical information.	1.1	OR.1
09/04/86	Submitted additional clinical information.	1.1	OR1
09/09/86	Letter from FDA establishing a new due date of November 4, 1986.	1.1	OR1
10/13/86	Letter to FDA informing them of our intent to excercise orphan drug exclusivity once NDA is approved.	1.1	OR.1
10/22/86	FDA deficiency letter concerning clinical data and manufacturing and controls.	1.1	OR.1
08/14/87	Submitted deficiency response to FDA letter of 10/22/86.	1.1	OR.1
10/16/87	FDA approvable letter for original application with request for further information.	1.1	OR.1
10/28/87	Letter to FDA to inform them of intent to amend application by 11/13/87.	1.1	OR.1
11/12/87	Submitted amendment to original application per FDA request in 10/16/87 approvable letter.	1.1	OR.1
12/07/87	Amendment to Chemistry, Manufacturing and Controls section.	1,1	OR.1
12/23/87	FDA approval of original application.	1.1	OR.1
01/25/88	Letter to FDA correcting typographical error (patent No.) in our August 1987 amendment.	1.1	OR.1

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### NDA 19-530

## Ucephan Oral Liquid

DATE	SUBJECT	LOCAT	TAB	
01/26/88	Letter from FDA granting seven years exclusivity.	1.1	OR.1	1